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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/646,985	11/17/2000	Mats Jarekrans	003300-679	3898

21839 7590 09/09/2003

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EXAMINER

SAUNDERS, DAVID A

ART UNIT PAPER NUMBER

1644

DATE MAILED: 09/09/2003

12

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

646,985

Applicant(s)

J AREKANS

Examiner

SAUNDERS

Group Art Unit

1644

—The MAILING DATE of this communication appears on the cover sheet beneath the correspondence address—

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, such period shall, by default, expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

Status

- ☒ Responsive to communication(s) filed on 8/19/02 & 9/13/02
- ☒ This action is FINAL
- ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- ☒ Claim(s) 1-12, 15-21 is/are pending in the application.
- Of the above claim(s) _____ is/are withdrawn from consideration.
- ☐ Claim(s) _____ is/are allowed.
- ☒ Claim(s) 1-12, 15-21 is/are rejected.
- ☐ Claim(s) _____ is/are objected to.
- ☐ Claim(s) _____ are subject to restriction or election requirement.

Application Papers

- ☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
- ☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.
- ☒ The drawing(s) filed on 12/11/02 is/are objected to by the Examiner. ARE APPROVED BY THE DRAFTSMAN.
- ☐ The specification is objected to by the Examiner.
- ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119 (a)-(d)

- ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- ☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been received.
- ☐ received in Application No. (Series Code/Serial Number) _____
- ☐ received in this national stage application from the International Bureau (PCT Rule 1.7.2(a)).

*Certified copies not received: _____

Attachment(s)

- ☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). 11
- ☐ Notice of Reference(s) Cited, PTO-892
- ☐ Notice of Draftsperson's Patent Drawing Review, PTO-948
- ☐ Interview Summary, PTO-413
- ☐ Notice of Informal Patent Application, PTO-152
- ☐ Other _____

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The amendments of 8/19/02 (Paper 8) and 9/13/02 (Paper 9) have been entered. Claims 1-12 and 15-21 are pending and under examination.

The following corrections have been entered in the previous Office Action:

At page 4, 5th line from top, changed "18" to -12--.

At page 6, 3rd line from bottom, changed "13" to -12--.

These changes have been entered in red ink and initialed and dated by the examiner.

The following objections and rejections of record remain and/or are modified due to applicant's amendments.

Claims 1-12 and 15-21 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

It is noted that applicant has amended the preamble and step (a) of claim 1 in order to encompass two embodiments, namely (1) obtaining leukocytes from blood or (2) obtaining leukocytes from a buffy coat fraction.

For the first of these embodiments claim 1 remains confusing for reasons of record (Paper 6, page 3, last paragraph). For this embodiment there would need to be an unrecited critical step of settling (page 2, line 20) prior to the filtration step. MPEP 2172.01. Like considerations apply to claim 12, which has provided no component in which to conduct a settling step.

It is noted that claim 10 has been amended to recite that a CIP and SIP step is performed. The claim, however, remains confusing because it gives no indication of

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where these steps occur, in relation to those recited in claim 1. Further, the added steps refer to "a system at site" but it is not clear what the components of the system may be. Are these components the filters, mixing device, etc recited in claim 1?

It is noted that applicant has amended claim 12 by stating that component (ii), which is now recited as a "retention vessel" achieves the lysis. It is noted that the examiner has ^{suggested} that applicant recite that lysis is achieved in the retention vessel. The claim is now confusing because both components (ii) and (iii) are recited as a "retention vessel"; what does that of (iii) accomplish?

Claim 12 is rejected under 112, second paragraph for failure to recite a critical, disclosed component of the apparatus –namely a static mixer. See page 8; see Figs. See original claims. See MPEP 2172.01 regarding failure to recite features disclosed as critical.

It is noted also that, while applicant has amended the preamble of claim 12 to cover two embodiments, as noted supra regarding claim 1, the claim is confusing because what is recited in feature (i) has not been amended to recite the two embodiments recited in the preamble.

In claim 18 "Apparatus" lacks antecedent basis in claim 11. Apparently applicant mistranscribed "12" in original claim 18 as "11".

Claims 1, 3-12 and 15-19 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make

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and/or use the invention. For the first embodiment of amended claim 1 (obtaining leukocytes from blood) applicant has disclosed no process or apparatus that enables "separating plasma from blood by filtration in order to achieve a filtered buffy coat fraction".

This is a repeat of the rejection of record (Paper 6, page 5, second para.).

Applicant's amendment to cover two embodiments (obtaining leukocytes from blood or from a buffy coat) has not overcome nonenablement of the first embodiment.

Claims 12 and 15-19 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. Applicant has disclosed no apparatus, which achieves lysis in a retention vessel, without having a static mixer provided in line, prior to the vessel. Unless the lysing agent and the cells are mixed prior to their entry into the retention vessel, one would not expect there to be adequate lysis of the unwanted red blood cells

This enablement rejection replaces that previously stated (Paper 6 page 6, first full para.) and has been necessitated by applicant's failure to correct claim 12 as suggested by the examiner.

Applicant's urgings filed on 8/19/02 and 9/13/02 have been considered but are unconvincing of patentability.

Applicant's amendment has necessitated the following 112 first paragraph rejection.

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Claims 12 and 15-19 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Applicant has entered new matter into claim 12 by virtue of deleting all references to a "static mixer". Nothing in the original specification, drawings or claims disclosed an apparatus without the "static mixer" of original claim 12, part (ii).

Applicant's urgings are convincing that the prior art rejection over Jones et al. should be withdrawn. The examiner concurs that the steps of claim 1, by virtue of referring to each preceeding step, must be conducted in order.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

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the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David A. Saunders, Ph.D., whose telephone number is (703) 308-3976. The examiner can normally be reached on Monday-Thursday from 8:00 a.m. to 5:30 p.m. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan be reached on (703) 308-3973. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number (703) 308-0196.

D. Saunders: jmr
Sept. 03, 2003

David A. Saunders
DAVID SAUNDERS
PRIMARY EXAMINER
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